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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,938	10/31/2001	Salvatore Albani	UCSD1360-1	8878

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/001,938

Applicant(s)

ALBANI ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57-59, 62-66 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-59, 62-66 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/10/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-56, 60, 61, and 67-73 have been cancelled.

Claims 57, 58, and 74 have been amended.

Claims 57-59, 62-66, and 74 are pending and are under examination as they read on the elected species of SEQ ID NO:3.

### ***Response to Arguments***

1. Applicant's response, submitted January 7, 2005 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Upon further consideration, the rejections of claims 57-59, 62-66 and 74 under 35 USC 112, first paragraph as not being enabled for how to make peptides that comprise sequences longer than the indicated SEQ ID numbers, and for lacking written description of the structure of such longer peptides, has been withdrawn.

4. Claims 57-59, 62-66 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended base claims 57 and 74 to incorporate the phrase "consisting essentially of" in reference to the polypeptide sequences of SEQ ID NOs: 1 to 26. This phrase does not have verbatim support in the specification or claims as originally filed. Further, the examples provided in the specification fail to provide meaning or context for this phrase. By these amendments, applicant has created a subgenus of the genus that contains polypeptides comprising SEQ ID NOs:1 to 26, but the boundaries of what is included in this subgenus are not clear. As such, the inclusion of these limitations into the claims is new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claim 74 under 35 USC 112, second paragraph as being indefinite has been withdrawn due to Applicant's amendment of the claim to remove the term "immune-response modulating".

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7. Claims 57-59 and 62-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Base claim 57 has been amended to recite a peptide consisting essentially of a sequence of one or more of SEQ ID NOs:1 to 26. The inclusion of the phrase "or more" makes the claim ambiguous. Specifically, does this claim indicate a single peptide that contains more than one SEQ ID NO (a fusion polypeptide that contains, for example SEQ ID NOs: 1 and 3) or does it indicate a mixture of polypeptides that differ in their sequence (for example, the peptides of SEQ ID NOs: 1 and 3 that are not covalently or non-covalently joined but yet are present together)? If fusion polypeptides are contemplated, does the "consisting essentially of " language allow for sequences other than those of SEQ ID NOs 1 to 26 be present in the fusion polypeptide? Claims that depend from base claim 57 do not provide clarification of these issues. Appropriate clarification of claim 57 is required.

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***Claim Rejections - 35 USC § 102***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 57-59, 62-66, and 74 stand rejected under 35 U.S.C. 102(b) as being anticipated by Carson et al., (US Patent No. 5,773,570, see entire document).

Applicant's arguments filed January 7, 2005 have been fully considered but they are not persuasive. Applicant has argued that the amendment of claims 57 and 74 to remove the term "comprising" and replace it with "consisting essentially of" removes the open ended nature of the claims. As such, Applicant has argued that the teachings of Carson et al. are no longer applicable since the teachings of Carson et al. are not limited to just SEQ ID NO:3 but instead teach full length dnaJ and fusion proteins that comprise the full length sequence of dnaJ.

The term "consisting essentially of" is not defined in the specification. As such, its meaning in relation to sequences is considered by the examiner to be open. Further, Applicant has provided no evidence that the additional sequences taught by Carson et al. impact the essential features of SEQ ID NO:3, and as such the claims are anticipated.

As stated in the previous office action, Carson et al. teach a purified antigenic *Escherichia coli* dnaJ protein that comprises SEQ ID NO: 3 and its use in a vaccine (column 2, lines 33-36, column 4, lines 52-54 and 62-67, and column 5, lines 1-4 and 13-16 in particular). Also disclosed are fusion proteins containing dnaJ (column 11, lines 22-31 and column 15, Example 1 in particular) that can be included in a pharmaceutical composition. Such compositions can include immunoadjuvants (paragraph spanning columns 5 and 6 in particular), such as Freund's complete or incomplete adjuvant (column 11, lines 38-41 in particular) or cytokines. Cytokines

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disclosed as particularly useful in the invention are the pro-inflammatory cytokine IL-6 (column 6, lines 2-5 in particular) and the anti-inflammatory cytokine TGF- $\beta$  (column 6, lines 24-32 in particular).

Since applicant's amendment has not altered the scope of the claim such that only SEQ ID NO:3 and no additional dnaJ sequence can be present, the teachings of Carson et al. still read on the instant claims.

Therefore, the teachings of the prior art anticipate the claimed invention.

10. No claims are allowable.

11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

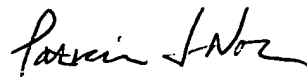
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 7, 2005

  
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